

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

### **I. Status of the Claims**

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 32-34 are requested to be canceled without prejudice or disclaimer.

Claims 28, 29, 31, and 35 are requested to be amended to correct minor typographical errors.

Upon entry of the foregoing amendments, claims 1-31 and 35 will be pending in this application, and claims 1-26 and 30 are withdrawn. Thus, claims 27-29, 31, and 35 are pending and subject to examination on the merits.

### **II. Declaration and Amendments After Final**

Applicants note that the Office Action is final. Nonetheless, Applicants respectfully request entry of the amendments and consideration of the declaration. More specifically, the amendment of claims 28, 29, 31, and 35 is clerical in nature and simplifies the issues for appeal. The declaration is being submitted to rebut a factual contention raised in the Office Action: “Cells in culture are considered to be compatible with physiological conditions an not incompatible with therapeutical use.” Because the Office did not earlier take the factual position that the cultures of the cited references “are considered to be compatible with physiological

conditions are not incompatible with therapeutical use,” the declaration could not be submitted earlier. *See* 37 C.F.R. § 1.116(e).

### **III. Withdrawn Claims**

Claim 30 is withdrawn “as being drawn to a non-elected invention.” Applicants understand that the scope of the search will be expanded to encompass claim 30 upon the elected species being found allowable. Indeed, claim 30 is dependent on generic claim 27.

### **IV. Claim Rejections – 35 U.S.C. § 102**

Claims 27-29 and 31-35 stand rejected as allegedly anticipated by Bhardwaj *et al.*, J. CLIN. INVEST. 98:715-722 (1996) as evidenced by Hackstein *et al.*, BLOOD 100(3):1084-1087 (2002) and Kelleher *et al.* INT’L IMMUNOLOGY 10(6):749-755 (1998). Each of these rejections is addressed separately below. However, each of the rejections shares a common flaw. The cited references fail to teach or suggest a “therapeutic composition.” Interpreting the cited references as disclosing a therapeutic composition runs far afoul of the understanding of one of skill in the art.

#### **A. Bhardwaj *et al.*, J. CLIN. INVEST. 98:715-722 (1996) as evidenced by Hackstein *et al.*, BLOOD 100(3):1084-1087 (2002)**

Claims 27-29 and 31-35 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by Bhardwaj as evidenced by Hackstein. The Office Action cites Bhardwaj as disclosing “a culture (i.e. a composition) comprising ex-vivo purified dendritic cells and IL-12,” and Hackstein is cited for disclosing that “dendritic cells arise from CD34+ stem cells.” Office Action at ¶ 5. “It is noted that the term ‘therapeutic composition’ carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition.” *Id.* Applicants respectfully traverse this ground of rejection.

“During patent examination, the pending claims must be ‘given their broadest reasonable interpretation consistent with the specification.’” MPEP § 2111 (citations omitted). However, “[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” *Id.* This broadest reasonable interpretation is based on the “ordinary and customary meaning” claim terms would have to one of ordinary to skill in the art. 2111.01(II).

Bhardwaj fails to anticipate the claimed invention, because Bhardwaj does not teach or suggest a “therapeutic composition,” as that term is understood to one of ordinary skill in the art. Bhardwaj discloses a cell culture that has both IL-12 and dendritic cells, which are either infected with influenza or uninfected. These compositions were used to evaluate the role of IL-12 in generating cytolytic T lymphocyte (CTL) responses to influenza virus. Bhardwaj does not, however, disclose a “therapeutic composition.”

The attached Declaration Under 37 C.F.R. § 1.132 of Michael T. Lotze (“Lotze Declaration”) establishes that one of skill in the art understand that a “therapeutic composition” is a composition suitable for administration to a patient for the treatment of some disease or condition. Lotze Declaration at ¶¶ 7, 9. These compositions are formulated so as to preserve the stability of the active agents while making the composition biologically compatible. *Id.* Thus, even if cell culture may be “physiologically compatible,” one of skill in the art would not necessarily understand that culture to be a “therapeutic composition.” In order to be a “therapeutic composition,” there must be some indication that the composition should actually be used in that manner. *Id.* Bhardwaj lacks any suggestion that it can be used for some therapeutic purpose.

Moreover, one of skill in the art would not consider Bhardwaj’s cell culture to be “physiologically compatible.” Lotze Declaration at ¶ 10. Bhardwaj’s crude culture contains agents, such as impurities, antithetical to a “therapeutic composition.” *Id.* Such a composition could cause serious complications if it were to be administered to a patient. *Id.* Accordingly,

one of skill in the art would consider Bhardwaj's cell culture to be unsuitable for use as a therapeutic agent. *Id.*

The Office Action argues that "[c]ells in culture are considered to be compatible with physiological conditions and not incompatible with therapeutical use." Office Action at ¶ 5. However, Bhardwaj's cell culture would not be considered a "therapeutic composition" to one of skill in the art, as discussed above. Moreover, Bhardwaj's cell culture would not be expected to be suitable for therapeutic use. Accordingly, Bhardwaj fails to anticipate the claimed invention.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

**B. Kelleher *et al.* INT'L IMMUNOLOGY 10(6):749-755 (1998)**

Claims 27-29 and 31-35 stand rejected under 35 U.S.C. § 102 as allegedly anticipated by Kelleher *et al.* INT'L IMMUNOLOGY 10(6):749-755 (1998). According to the Office Action, "Kelleher *et al.* disclose a culture (i.e. a composition) comprising dendritic cells and IL-12 (see pg. 750 in particular)." Office Action at ¶ 6. Applicants respectfully traverse this ground of rejection.

Kelleher fails to anticipate the claimed invention, because Kelleher does not teach or suggest a "therapeutic composition." Instead, Kelleher discloses cultures comprising dendritic cells. IL-12 was added to some of these cultures to determine "whether IL-12 administration during DC maturation altered cell numbers, phenotype and function." Kelleher at 749, right col. The dendritic cells were cultured in "RPMI 1640 (Dutch modification; Sigma, Poole, UK) supplemented with 10% FCS (Gibco, Paisley, UK), 100 U Penicillin (Gibco), 100 µg/ml streptomycin (Gibco), 2 mM glutamine (ICN Flow, Irvine, UK), 2 mercaptoethanol 10<sup>-5</sup> M (Sigma)." *Id.*

As discussed above, the attached Lotze Declaration establishes that one of skill in the art understand that a “therapeutic composition” is a composition suitable for administration to a patient for the treatment of some disease or condition. Lotze Declaration at ¶¶ 7, 9. In order to be a “therapeutic composition,” there must be some indication that the composition should actually be used in that manner. *Id.* Kelleher lacks any such teaching.

Moreover, one of skill in the art would not consider Kelleher’s cell culture to be “physiologically compatible.” Lotze Declaration at ¶ 10. Kelleher’s crude culture contains agents, such as impurities, antithetical to a “therapeutic composition.” *Id.* Such a composition could cause serious complications if it were to be administered to a patient. *Id.* Accordingly, one of skill in the art would consider Kelleher’s cell culture to be unsuitable for use as a therapeutic agent. *Id.*

The Office Action argues that “[c]ells in culture are considered to be compatible with physiological conditions an not incompatible with therapeutical use.” Office Action at ¶ 6. However, Kelleher’s cell culture would not be considered a “therapeutic composition” to one of skill in the art, as discussed above. Moreover, Kelleher’s cell culture would not be expected to be suitable for therapeutic use. Accordingly, Kelleher fails to anticipate the claimed invention.

For at least these reasons, Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

**V. Claim Rejections – 35 U.S.C. § 112, Second Paragraph**

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly unclear for reciting “antigen present cell.” “since it is grammatically incorrect.” Office Action at ¶ 7.

One of skill in the art would clearly understand the metes and bounds of claim 28 espite the obvious typographical error. Nonetheless, Applicants have corrected the obvious typographical error, so claim 28 now recites “antigen presenting cell.”

**VI. Claim Rejections – 35 U.S.C. § 112, First Paragraph**

Claims 32-34 stand rejected under 35 U.S.C. § 112, first paragraph. More specifically, claim 34 stands rejected as allegedly lacking written description support, and claims 32-33 stand rejected as allegedly lacking enablement. Office Action at ¶¶ 9-10.

While not acquiescing in the propriety of the rejection, Applicants have canceled claims 32-34. Thus, these ground of rejection are rendered moot.

### CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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